BY ELECTRONIC SUBMISSION VIA ABXordinance@sfgov.org

April 5, 2018

San Francisco Department of Environment
1455 Market Street
Suite 1200
San Francisco, CA 94103

Re: Ordinance No. 204-17; Regulations for Antibiotic Use in Food Animals Ordinance

The National Pork Producers Council (NPPC) has significant concerns with Ordinance No. 204-17 (the Ordinance) and Regulation SFE-18-01-AUIFA (Draft Regulations) implementing the Ordinance, including its draft reporting form. Taken together, they create an unworkable reporting and labeling scheme for meat products. Because of its deep fundamental flaws, lack of basic knowledge or understanding of either the domestic or international livestock and meat supply chain, and the confusion created by its conflict with existing regulatory programs, NPPC strongly urges the city of San Francisco to reconsider and rescind Ordinance No. 204-17 and the proposed regulations.

NPPC is an association of 43 state pork producer organizations that serves as the voice for the nation’s pork producers. The U.S. pork industry represents a significant value-added activity in the agriculture economy and the overall U.S. economy. Nationwide, more than 60,000 pork producers marketed more than 118 million hogs in 2016, and those animals provided total cash receipts of nearly $24 billion. Overall, an estimated $23 billion of personal income and $39 billion of gross national product are supported by the U.S. pork industry. Pork producers are strong and vital contributors to value-added agriculture in the United States, and are deeply committed to the economic health and vitality of our businesses and the communities that our livelihoods help support. Just as importantly, though, pork producers take a broad view of what it means to be responsible farmers and business people, and what it takes to be good neighbors as well. We take this responsibility with the utmost seriousness and commitment, and it is in this spirit that our producer members see their mission as two-fold: to provide a growing world population with safe, nutritious and affordable pork raised in the most sustainable method possible, and to ensure that the animals we tend receive the highest degree of care and attention. One of the keys to this effort is the judicious use of antibiotics to treat, control or prevent disease in their animals.

NPPC, and the pork producers we represent, have made sustained, long term, commitments to fully understanding and addressing antibiotic resistance. For the past 20 years, American pork producers, working with the Food and Drug Administration (FDA), have proactively taken steps to address and combat antibiotic resistance. Our producers and veterinarians are the experts when it comes to antibiotic use in their animals, and if invited, would have proved to be tremendous resources for members of the City Council when they were originally contemplating this
measure. Unfortunately, the failure of either the San Francisco City Council or its Department of the Environment to engage proactively with the best subject matter experts on this issue has resulted in the current unnecessary and duplicative ordinance that will result in reduced consumer choices, increased food prices, and misleading information. Accordingly, NPPC strongly urges the City of San Francisco to rescind Ordinance No. 204-17.¹

1. The Ordinance was enacted without clear evidence demonstrating that antibiotic use in food animals poses a risk to consumers in San Francisco.

NPPC agrees that the issue of antibiotic resistance is an important public health concern. However, the facts and best available science make clear that San Francisco’s underlying premise, that antibiotic use in food animals is the major contributing factor to this public health problem, is wrong. The 2013 report from the Centers for Disease Control and Prevention cited in Section 2701(b) of the Ordinance makes clear that foodborne antimicrobial resistance is not the main contributor of deaths from resistant micro-organisms. While even one death is too many, and a tragedy, out of more than 23,000 estimated food-related deaths reported, only 66 were attributed to resistant foodborne infections of Campylobacter and non-typhoidal Salmonella.

Even more compelling is the significant body of peer-reviewed literature on the quantitative risk of using antimicrobials in food animal production. The following peer-reviewed articles provide compelling evidence that the current uses of many of the antibiotics administered to food animals do not present a significant risk to human health and, indeed, may serve to protect public health by helping ensure lower microbial loads on animal products:


¹ NPPC is also supportive of the comments filed by the North American Meat Institute, a trade organization that also represents the interests of the U.S. pork industry.
predicted risk of suboptimal human treatment of infection with C. coli from swine is only 1 in 82 million, with the risk from C. jejuni in poultry or beef being even less.

- Lis Alban, Elizabeth Okholm Nielsen and Jan Dahl, A human health risk assessment for macrolide-resistant Campylobacter associated with the use of macrolides in Danish pig production, 83(2) Preventive Veterinary Medicine 115-129 (2008), http://www.ncbi.nlm.nih.gov/pubmed/17659797. This risk assessment concluded that the risk associated with veterinary use of macrolides in Danish pigs for human health seemed to be low.

- Louis A. Cox & Douglas A. Popken, Assessing potential human health hazards and benefits from subtherapeutic antibiotics in the United States: tetracyclines as a case study, 30(3) Risk Analysis 432-457 (2010), http://www.ncbi.nlm.nih.gov/pubmed/20136749. This paper concluded that quantitative risk assessment and empirical data indicate that continued use of subtherapeutic antibiotics in the United States has not harmed human health, and bans in Europe have not helped human health. Specifically, tetracycline uses and resistance patterns suggest there is no significant human health hazard from continued use of tetracycline in food animals.

- H. Gregg Claycamp & Barry H. Hooberman, FDA Center for Veterinary Medicine, Risk Assessment of Streptogramin Resistance in Enterococcus faecium Attributable to the Use of Streptogramins in Animals (Nov. 2004), http://www.fda.gov/OHRMS/DOCKETS/98fr/2004n-0479-ra00001.pdf. FDA’s own published risk assessment regarding the association between streptogramin use in animals and treatment failure of E. faecium in people found the risk to be from 0.7 to 14 chances in 100 million per year.

- Louis A. Cox & Douglas A. Popken, Quantifying human health risks from virginiamycin used in chickens, 24(1) Risk Analysis 271-288 (2004), http://www.ncbi.nlm.nih.gov/pubmed/17270298. This model showed that the theoretical statistical human health benefits of a ban range from zero to less than one statistical life saved in both Australia and the United States over the next five years and are rapidly decreasing.

- Paul S. Singer et al., Modeling the relationship between food animal health and human foodborne illness, 79(2-4) Preventive Veterinary Medicine 186-203 (2007), https://www.ncbi.nlm.nih.gov/pubmed/17270298. This model examined the potential human health risks and benefits from interventions such as the continued use of antibiotics in animal agriculture. The model showed that small improvements in food animal health would likely result in significant reductions in human illness.

human health risks from more pathogens reaching consumers if virginiamycin use was terminated were predicted to far outweigh benefits of reduced streptogramin-resistant vancomycin-resistant *Enterococcus faecium*.

The already limited and decreasing, impact of antibiotic resistance in foodborne infections to the overall picture of the public health antibiotic resistance problem is further demonstrated by the National Antimicrobial Resistance Monitoring System reports of a decreasing prevalence of antimicrobial resistance in human Salmonella cases. In 1996, over 35% of cases had some form of resistance while by 2012 that number had fallen to approximately 15%.

In justifying its need, the Ordinance cites a reduction in the gross amounts of antimicrobials used in Denmark as well as claims of increases in pork production of 50%. While there have been increases in the numbers of pigs born in Denmark, more than 33% of those pigs are now exported to other countries as young animals to be grown and harvested. Thus, the points in the life when the largest amounts of antibiotics would be used now occur in other countries such as Poland and Germany. In fact, the kilograms of pork produced in Denmark has fallen from a high of 3,204 million kilograms in 2006 to only 1,943 million kilograms in 2016. Additionally, the Ordinance failed to acknowledge that there was no demonstrated positive public health impact associated with Denmark’s reported decreases in antibiotic use in food animals. From 2006 to 2016, Denmark experienced a steady increase in the prevalence of antimicrobial resistant Salmonella in not only pigs, but also in domestically produced pork and non-travel-related human foodborne illness cases. The Danish example cited is perhaps one of the strongest arguments for why the Ordinance will fail to provide any public health benefits.

Antimicrobial Stewardship, that is the careful use of antibiotics with veterinary oversight at the correct dose, the right duration and for the identified disease problem, is a cornerstone of programs such as the Pork Quality Assurance Plus program (PQA Plus) – an education and assessment program developed by veterinarians and farmers who understand the real-world challenges faced in producing safe, wholesome and plentiful pork products. Through programs such as PQA Plus, along with robust federal oversight, consumers worldwide, as well as those in San Francisco, can be assured that pork produced in the United States is produced by farmers observing good antimicrobial stewardship principles.

Because there is no demonstrated risk to consumers in San Francisco, Ordinance No. 204-17 should be rescinded.

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3 Id.


5 PQA Plus is an educational program representing the pork industry’s commitment to continuous improvement of production practices, including antibiotic stewardship. It was created in 1989 and is revised every three years. See https://www.pork.org/certifications/pork-quality-assurance-plus/.
2. The complex and robust statutory and regulatory scheme created by the Food, Drug, and Cosmetic Act and the Federal Meat Inspection Act demonstrates the intent of Congress to occupy the field of antibiotic use in food animals.

The Food, Drug, and Cosmetic Act (FDCA) together with the Federal Meat Inspection Act (FMIA) and implementing regulations create a comprehensive regulatory scheme that protects the health and welfare of animals treated with animal drugs as well as the health of consumers who consume products from treated animals.6

Under the authority of the FDCA, FDA is responsible for approving human and animal drugs. All drugs must undergo years of clinical trials and evaluations and ultimately demonstrate that they are safe and effective before they can be sold in interstate commerce.

For antimicrobials to be used in food animals, the FDA requires companies to conduct risk assessments to ensure that the antibiotic will not present a significant risk to human health from exposure to antibiotic resistant bacteria in meat and poultry products.7 Companies must also conduct studies to determine a safe level of any residues that may remain in the animal after treatment with the antibiotic. Based on that safe level, the FDA establishes a mandatory drug withdrawal time that must be followed before the animal can be processed for food.8

The National Residue Program conducted by the Food Safety and Inspection Service (FSIS) of USDA is responsible for testing and ensuring all meat and poultry products are free from any harmful levels of antibiotics.9 Additionally, under the FMIA, all processing facilities must conduct a hazard analysis to determine the food safety hazards reasonably likely to occur in the production process, including those arising from drug residues, and identify the preventive measures the establishment can apply to control those hazards.10

Together these regulatory safeguards combine to create a comprehensive framework that certifies the safety of our nation’s meat and poultry supply. Further, the pervasiveness of the federal regulatory system created by the FDCA and FMIA demonstrates the intent of Congress to occupy the field of antibiotic use in food animals; thus, leaving no room for the City of San Francisco to also regulate antibiotic use in food animals. Consequently, Ordinance No. 204-17 should be rescinded.

3. FDA’s and USDA’s approach is the most effective for limiting antibiotic resistance and providing accurate data on antibiotic use.

7 “If the drug is an antibiotic intended for food-producing animals, the sponsor also conducts human food safety studies to assess the number of antibiotic-resistant bacteria that will potentially enter the food supply in or on food products made from treated animals.”
https://www.fda.gov/AnimalVeterinary/ResourcesforYou/AnimalHealthLiteracy/ucm219207.htm
8 21 C.F.R. Part 556.
10 9 CFR 417.2.
In addition to initially approving the safety and effectiveness of animal drugs, FDA has taken several regulatory measures to combat antibiotic resistance, all of which have received the support of the livestock and animal health industries.\(^\text{11}\)

- The National Antimicrobial Resistance Monitoring System (NARMS), established in 1996, is a collaborative program among FDA, USDA, and the CDC that monitors antibiotic resistance in foodborne bacteria and allows FDA and other public health agencies to make data-driven decisions regarding the effectiveness of antibiotics for humans and animals.

- FDA Guidance 209 and 213 directed pharmaceutical companies, veterinarians, and farmers to discontinue use of medically important antibiotics for weight gain and growth promotion purposes by Jan. 1, 2017.\(^\text{12}\) Of the 292 animal drugs affected by Guidance 213, 84 were completely withdrawn, 93 were converted from over-the-counter status to veterinary feed directive status, 115 were converted from over-the-counter status to veterinary feed directive status, and all 31 labeled for growth-promotion were relabeled to preclude such uses.\(^\text{13}\)

- The Veterinary Feed Directive (VFD) prohibits the use of medically important antibiotics in animal feed unless ordered by a licensed veterinarian to address disease concerns. Since the Animal Medicinal Drug Use Clarification Act prohibits extra-label use of drugs in animal feeds, it is illegal to use any medically important antimicrobial to improve growth or nutritional efficiency. The label changes compelled under Guidance 213 require a prescription for any medically important antibiotics administered in water.

- While FDA currently publishes data on the annual sales of antibiotics for food animals by species, it has been criticized for not providing granular data on how antibiotics are used on-farm. Thus, USDA and FDA are collecting nationally representative data on the amounts and indications, for on-farm antimicrobial use. The USDA National Animal Monitoring System conducted national surveys on antimicrobial use and stewardship starting in 2017 to assess how on-farm use has changed with the implementation of Guidance 213. Additionally, FDA has grants to researchers to collect more granular, representative data on on-farm antibiotic use in dairy production, beef feedlots, swine production and poultry production.

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\(^{11}\) See e.g. *Animal Health Institute Issues Statement Regarding Antimicrobial Use Plan*, NATIONAL HOG FARMER, (Dec. 13, 2013) http://nationalhogfarmer.com/health/animal-health-institute-issues-statement-regarding-antimicrobial-use-plan (“animal health companies have supported this policy since it was announced in 2012 and will continue to work with FDA on its implementation.”).

\(^{12}\) It should also be noted that under the FDCA, medically important antibiotics cannot continue to be used for growth promotion under the guise of disease prevention. *See 21 C.F.R. §530.10; see also* William Flynn, FDA Center for Veterinary Medicine, Deputy Director for Science Policy, June 2016 Presentation President’s Advisory Council on Combating Antibiotic-Resistant Bacteria (“Once changes are made to affected products, it will be illegal to use products for growth promotion or to use without the authorization of a licensed veterinarian.”).

Together these programs culminate into a successful and comprehensive regulatory framework that demonstrates the adequacy and effectiveness of FDA and USDA oversight of antibiotic use in food animals.

4. **The joint and several liability provision is fundamentally flawed and unfair.**

Section 2705(c) of the Ordinance currently establishes joint and several liability for Grocers and Producers for violations of the Ordinance, to be assessed in the form of “administrative penalties, including fines for violations of this Chapter 27 and/or any regulation adopted pursuant thereto, and/or suspension or revocation of any permits held.” The Ordinance specifies that “[e]ach day a Grocer fails to correct a violation shall constitute a separate violation” for purposes of calculating administrative fines.

As an initial matter, it is important to recognize that the doctrine of joint and several liability serves to deter bad conduct and provides that every defendant whose conduct contributed to an indivisible injury, no matter how slight, may be held liable for all of damages. Actual deterrence, however, can only be achieved when the harm at issue results from the conduct of the defendant. The Draft Regulations illustrate how the joint and several liability scheme established by the Ordinance, which makes Producers liable for violations committed by Grocers, is unworkable.

The Draft Regulations expressly state that “[c]ompliance with the Antibiotic Use in Food Animals Ordinance requires that a Grocer report antibiotic use policies and practices” to the City agency (Section D 1.1). Additionally, “Grocers must maintain documentation regarding each meat and poultry Producer’s antibiotics use for five (5) years from filing the report” (Section D 1.3). And only “[a] Grocer may request a waiver” of the reporting requirements (Section D 2.0). The Ordinance thus creates, and the Draft Regulations reinforce, complete liability for Producers who have no control over whether a violation ever occurs, or whether a violation is ever corrected. This creates a fundamental unfairness to Producers and does not further the goal of deterrence.

In addition, there is no basis in California state law or San Francisco municipal law for the type of “no-fault” joint and several liability that the Ordinance seeks to establish. Indeed, San Francisco administrative law itself forecloses this statutory scheme, as highlighted by San Francisco’s own administrative review process. Admin. Code § 100.8, incorporated by reference into the Ordinance, creates the right to appeal a “citation” (i.e., notice of violation of an ordinance – see Admin. Code § 100.2), and provides that a person who has received a citation may appeal that citation on the grounds that (i) there was no violation of the ordinance for which the citation was issued, or that (ii) the person cited did not commit the violation. Because the Ordinance only imposes obligations on the Grocers—as the Draft Regulations themselves acknowledge—only Grocers can “violate” the Ordinance. But under Section 2705(c)’s joint and several liability provision, Producers can be held 100% liable each time a Grocer violates the Ordinance, even though Producers themselves are incapable of violating or correcting violations of the Ordinance. Indeed, a Producer who has provided all required information to a Grocer for its report can be held 100% liable for the failure of the Grocer to file that report. In such a case, joint and several liability does not deter bad conduct, and in fact punishes good conduct.
Furthermore, there is no precedent in San Francisco law for the expansion of joint and several liability to include this type of “no-fault” liability of Producers. In every other instance where joint and several liability is imposed in the statutory law of San Francisco, the situation involves an agency relationship (e.g., employer-employee, contractor-subcontractor), or is expressly described as applying where “two or more persons” are “responsible” for committing a particular statutory violation. This Ordinance is the first San Francisco statute to impose no-fault joint and several liability for actions of persons other than agents, where there is no personal fault to serve as the basis for the Producers’ liability. The resulting scheme is unworkable, fundamentally unfair, and is foreclosed by the administrative review process guaranteed by Admin. Code § 100.8.

Even if the Ordinance were amended to impose obligations directly on Producers, such an amendment would not solve the fundamental unfairness problem and would introduce additional terminal defects. The Ordinance fails to consider the supply chain for the goods it seeks to regulate. Many affected Producers are outside the state of California and sell their products (ranging from an animal to an animal product) to middle men, many of whom are also out-of-state. The middle man may then resell the animal or product to other middle men, in or out of state, or directly to a Grocer in San Francisco. It is in fact common for a product to go through many hands between the Producer and its end point of a grocer’s shelf.

Logistically, it is very difficult, if not impossible, for a Producer to know if and when his or her animals are sold to a Grocer in San Francisco. Thus, if the City amends the Ordinance to impose obligations directly on Producers, it will effectively be regulating conduct by the Producers—i.e., the sale of food animals to middle men—that occurs entirely out-of-state. This type of regulation is virtually per se invalid under the Commerce Clause of the U.S. Constitution. As the U.S. Supreme Court has recognized, “a statute that directly controls commerce occurring wholly outside the boundaries of a State exceeds the inherent limits of the enacting State’s authority and is invalid regardless of whether the statute’s extraterritorial reach was intended by the legislature.” The Ninth Circuit has agreed: “a state law [that] directly affects transactions that take place … entirely outside of the state’s borders … is invalid per se.” Accordingly, attempts to amend the Ordinance to address the issues raised herein would be futile, and thus Ordinance No. 204-17 should be rescinded in its entirety.

5. The City’s proposed regulations will not accomplish the stated goals of Ordinance No. 204-17; instead, they will only create consumer confusion by producing misleading information.

While the Ordinance states that San Francisco “can play a pivotal role in …[i]increasing transparency of antibiotic use practices,” the data collected is likely to only further add to any

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16 Valley Bank of Nev. v. Plus Sys., Inc., 914 F.2d 1186, 1189-90 (9th Cir. 1990).
existing confusion. The data collected by each store will duplicate data collected by other stores, without an easy way for the San Francisco Department of the Environment to identify and account for such duplication. The data reported by each store or chain is likely to also represent data on meat from animals that may also have been shipped to other stores or chains. Since the Ordinance asks for the total number of animals each producer owns and the total amount of antibiotics administered, each store could report data from the same producer, leading to counting the same animal(s) multiple times. Even more confusing, each animal may contribute to multiple cuts. For example, market hog carcasses are split into halves, and each half contributes to five primal cuts. Each primal cut is then further fabricated into the cuts that are seen in a grocery store. For example, the USDA Institutional Meat Purchases Specifications list 17 different cuts that can come from just the pork leg. Each one of those would have a different name or SKU in the grocery store. The same would hold true for shoulders, bellies and loins as well as heads and feet. The potential number of cuts that a farmer’s animals may be sold in the retail meat case is staggering, and thus any potential estimate from the data collected in San Francisco will be grossly inflated and unable to provide any analytical value or added transparency.

Additionally, neither the Ordinance nor the proposed regulations adequately describe how information collected from grocers will be quantified and reported to consumers. European countries have experimented with reporting metrics such as Animal Daily Doses, or Population Corrected Units, gross weight by active ingredient or antibiotic salts, or even mg of use over kg of live animal, meat or milk produced. Each of these reporting schemes has proved to have advantages and disadvantages. And, comparison between countries or species is difficult because of different production practices such as average slaughter weight or carcass yield. Without significant input and discussion on reporting metrics, San Francisco will add confusion to the consumers as they attempt to make informed buying decisions.

As described earlier, the USDA and FDA work to ensure that no unsafe residues of animal health products remain in meat or milk. By focusing on the amount(s) of antibiotics that have been legally administered to animals to address disease concerns while failing to account for observed withdrawal times, the Ordinance will only propagate confusion about antibiotic use in the meat consumers purchase.

The Ordinance cites California’s recently passed SB 27 as further adding to the “confusing mix” consumers must navigate around labeling and antibiotics. If taken as true, this statement logically invites the question: How will adding yet another layer of regulation at the local level bring clarity to this “confusing mix,” particularly when there has been no proposed system for quantifying or explaining collected information? If transparency and clarity are the end goals of the City Council, Ordinance No. 204-17 should be rescinded.

6. Consumers will ultimately pay the price for this flawed ordinance.

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17 Ordinance No. 204-17 only vaguely states that: “the Department will publish its findings on its website and may disseminate its findings through other means deemed appropriate.”
The consumer is the cited reason for the Ordinance, yet, ironically, it is the consumer who will suffer the most because of the multitude of unintended consequences that come with implementing the Ordinance.

Creation of the proposed unnecessary, burdensome reporting requirements carry a cost of compliance for Grocers. In turn, Grocers would incur costs from searching, screening, monitoring, policing and enforcing the Ordinance throughout their supply chains. In a low-margin sector such as grocery retail, these costs cannot and will not be borne by the retailer; they will instead be passed on to the consumer in the form of higher food prices.

It is entirely possible supply chain participants may determine that the marginal costs of compliance are not worth the marginal revenue of doing so, resulting in a reduction in the number of product groups offered and/or the number of suppliers participating in the market. Currently, San Franciscans have a choice in meat products available for purchase. Customers seeking meat products from animals raised without antibiotics can find and purchase such products. Likewise, customers seeking traditionally-raised, less-costly meat products can find their desired choice of product. However, it is entirely possible, if not guaranteed, that San Franciscans will lose this choice if these regulations are finalized, and while proponents of Ordinance No. 204-17 may welcome this outcome, those without the resources to pay a premium for their source of nutritious protein, likely will not.

If the consumer is truly the concern of the City of San Francisco, NPPC strongly encourages the Department of Environment and the City Council to consider these unintended consequences and rescind Ordinance No. 204-17.

Thank you for your consideration of these comments. Please do not hesitate to contact NPPC staff should you have any questions or require further clarification of our position.

Sincerely,

Jim Heimerl
President
National Pork Producers Council